

QZ ASV Gynäkologische Tumore Hildesheim

aktuelle klinische Studien in der Gynäkologischen Onkologie

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PVA Mammographie-Screening Niedersachsen Süd

Hildesheim, den 20.4.2026

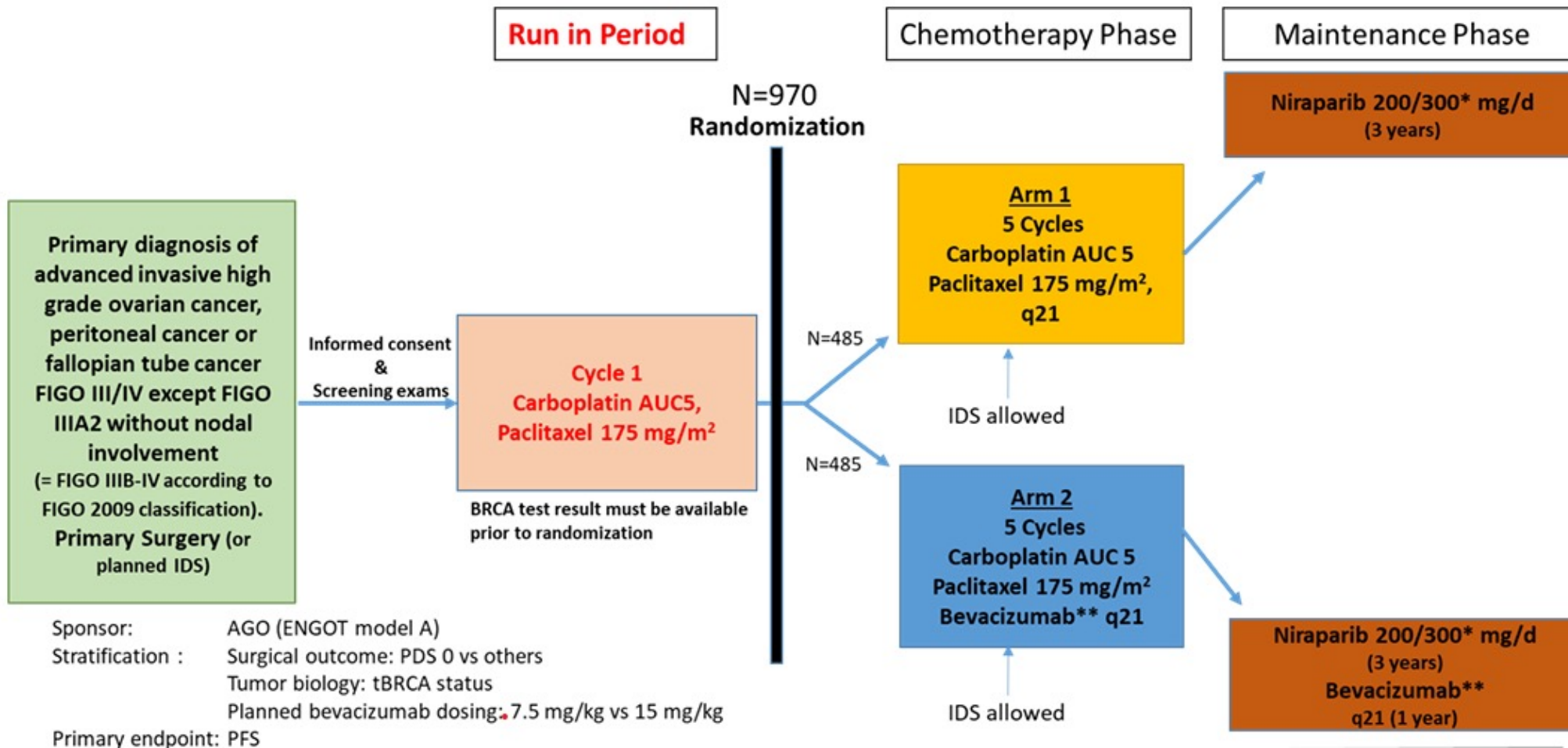
Gynäkologische Karzinome

Fortgeschrittenes Ovarialkarzinom: Ovar-28-Studie

- Gesetzt ist die postoperative Chemo mit 6xCarboplatin/Taxol
- Unklar ist die beste **Erhaltungstherapie**
 - Ob mit einem Angiogenesehemmer
 - Oder einem Parp-Inhibitor
 - Zur Blockade der DNA-Reparatur
 - Oder der Kombination von beidem
- Nach Studienlage sind zugelassen
 - Bevacizumab
 - im Stadium IIIB, IIIC und IV mit und nach Carbo/Taxol
 - Olaparib
 - im Stadium III/IV nach Carbo/Taxol beim G3 serösen mBRCA Ovarialkarzinom (Solo1-Studie)
 - Olaparib + Bevacizumab
 - im Stadium III/IV nach Carbo/Taxol beim G3 serösen HRD Ovarialkarzinom (Paola1-Studie)
 - Niraparib
 - im Stadium III/IV nach Carbo/Taxol beim G3 serösen Ovarialkarzinom (Prima-Studie)

AGO-OVAR 28 / ENGOT-ov57

rekrutierend

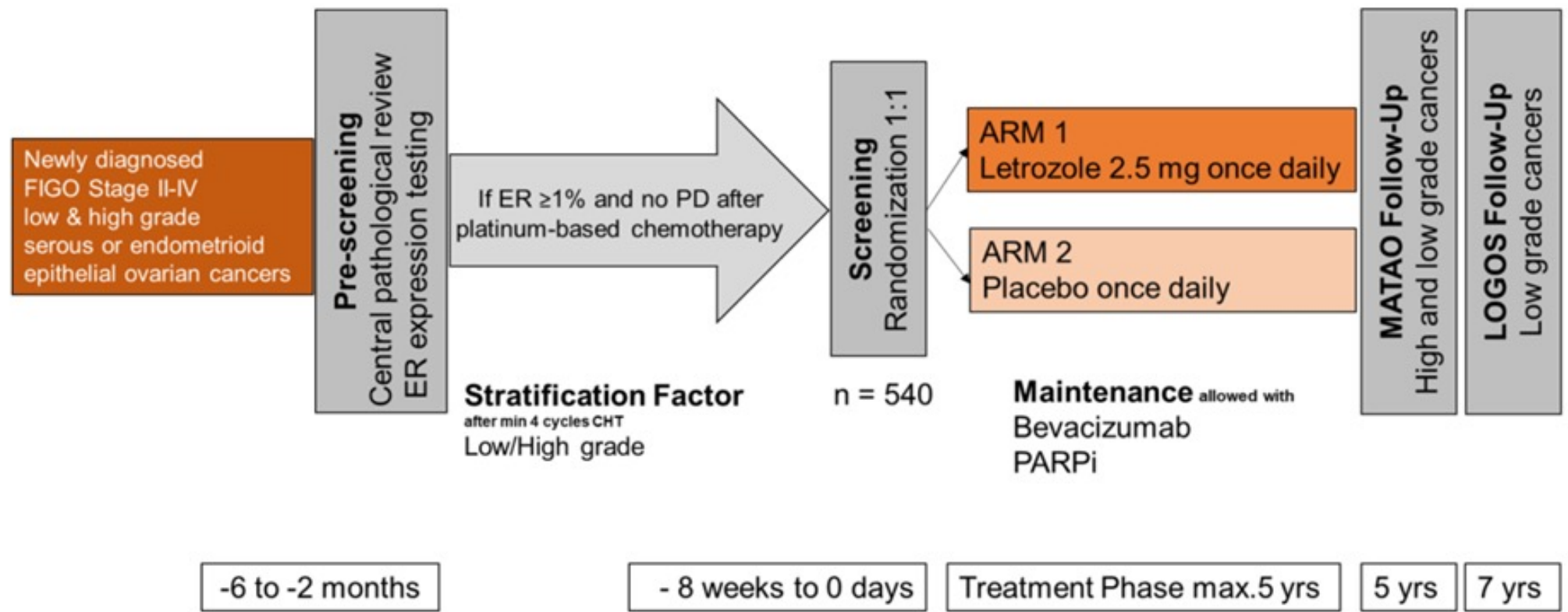


3 Patientinnen randomisiert

Ovarialkarzinom: MATAO-/Engot-54-/Swiss-GO-2

- Gesetzt ist die postoperative Chemo mit 6xCarboplatin/Taxol
- Unklar ist die beste **Erhaltungstherapie**
 - Ob mit einem Angiogenesehemmer
 - Oder einem Parp-Inhibitor
 - Zur Blockade der DNA-Reparatur
 - Oder der Kombination von beidem
- und/oder eine endokrine Therapie mit einem Aromatasehemmer
- Rationale: 30-80% aller OC exprimieren Hormonrezeptoren

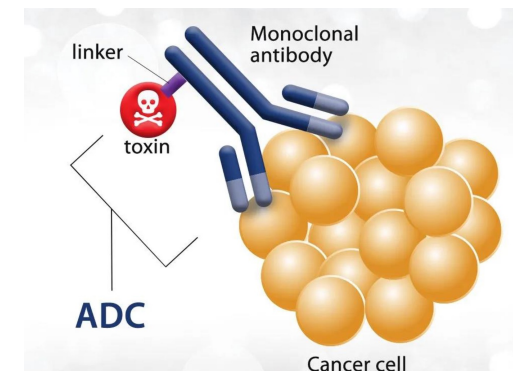
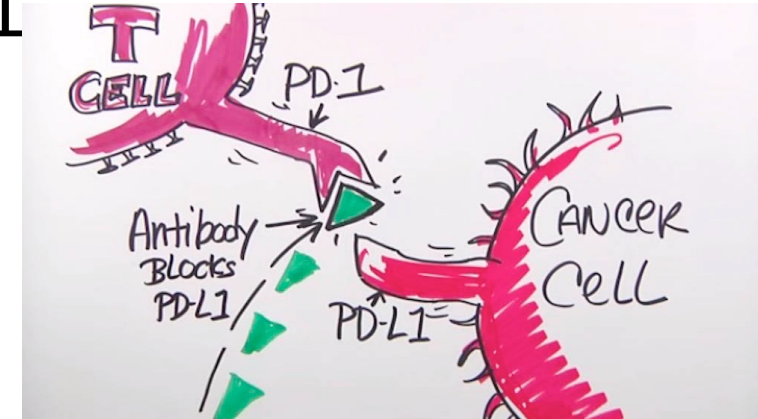
MAintenance Therapy with Aromatase inhibitor in epithelial Ovarian cancer: a randomized double-blinded placebo-controlled multi-center phase III Trial (ENGOT-ov54/Swiss-GO-2/MATAO) including LOGOS (Low Grade Ovarian cancer Sub-study) **rekrutierend**



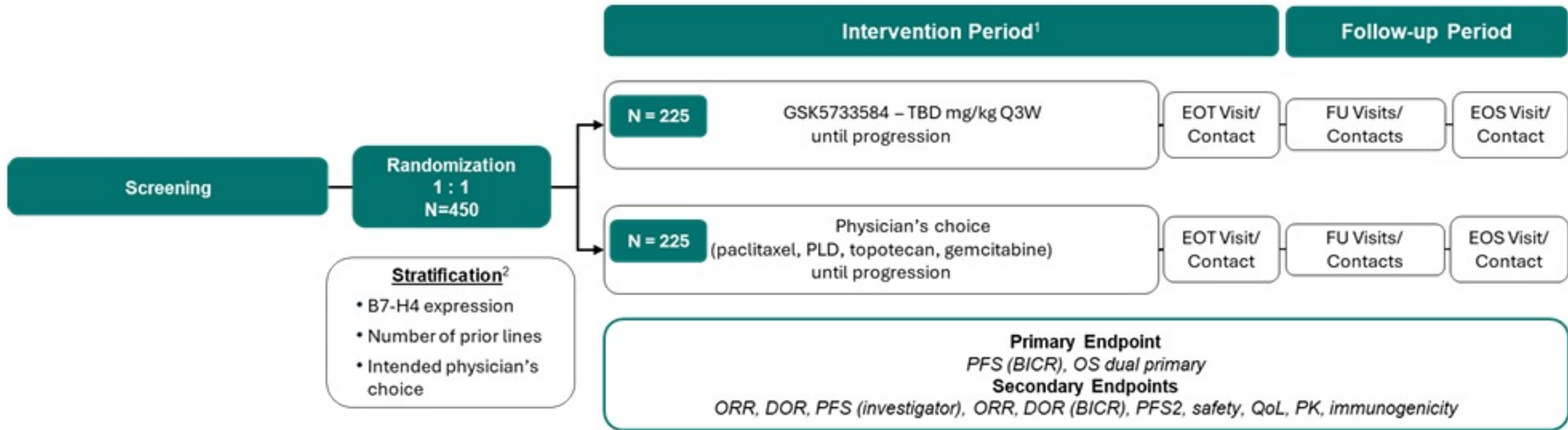
1 Patientin randomisiert

Ovarialkarzinom: BEHOLD-Ovarian01

- Standardtherapie des rezidierten epithelialen
- **Platinresistenten** Ovarialkarzinoms
- ist eine erneute Chemotherapie
 - mit Paclitaxel oder Topotecan oder Gemcitabine oder Caelyx
 - +/- Bevacizumab
- jüngst EMA-Zulassung auch für
 - Paclitaxel/Pembrolizumab +/- Bevacizumab
 - Falls PD-L1 ≥ 1
- GSK 5733584 ist ein neues Antikörper-Wirkstoffkonjugat
- An dem Antikörper > Protein B7-H4
- hängt ein Topoisomerasehemmer



A randomized, multicenter, open-label, Phase 3 study to evaluate GSK5733584 in comparison with chemotherapy in participants with platinum-resistant ovarian cancer (BEHOLD-Ovarian01) **in Planung**



Ovarialkarzinom: BEHOLD-Ovarian02

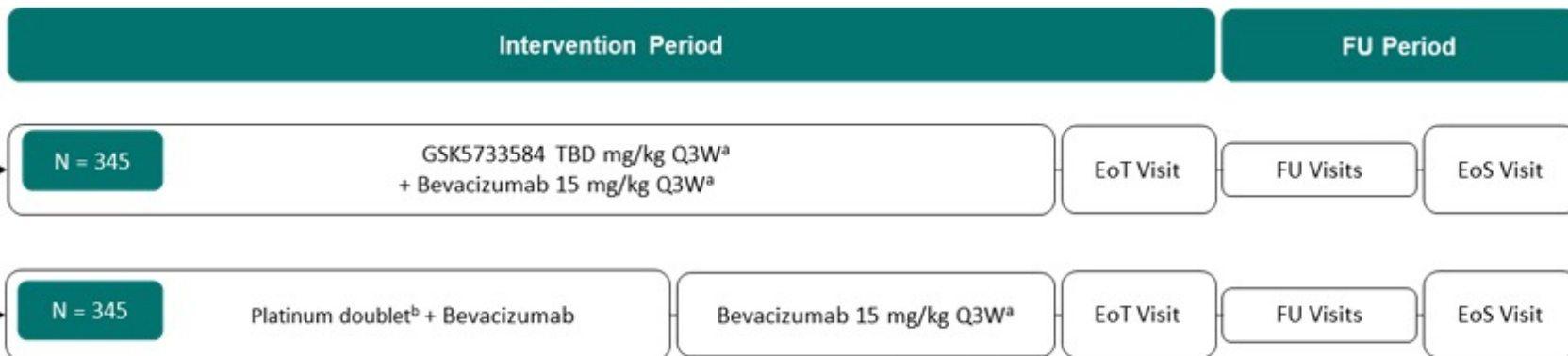
- Standardtherapie des rezidierten epithelialen
- platinsensitiven Ovarialkarzinoms
- ist eine erneute platinhaltige Chemotherapie
 - mit Bevacizumab
 - oder gefolgt von einem Parp-Inhibitor
- GSK 5733584 ist ein neues Antikörper-Wirkstoffkonjugat
- s.o.

A Randomized, Multicenter, Open-Label Phase 3 Study to Evaluate the Efficacy of GSK5733584 Combined with Bevacizumab Versus Platinum doublet Combined with Bevacizumab in Patients with Platinum-Sensitive Ovarian Cancer (BEHOLD-Ovarian02)

Population

- ≥18 years old
- Platinum-sensitive HGS/HGE ovarian cancer
- 1-2L prior therapy
- Received prior PARPi if BRCAm
- Prior bevacizumab permitted
- Secondary cytoreduction permitted
- FFPE tissue

R
1 : 1



Stratification

- B7-H4 expression (not evaluable or <25% / ≥25% to <50% / ≥50%)
- PFI (6-12 months / >12 months)
- Prior PARPi (yes / no)
- Prior secondary cytoreduction (yes / no)

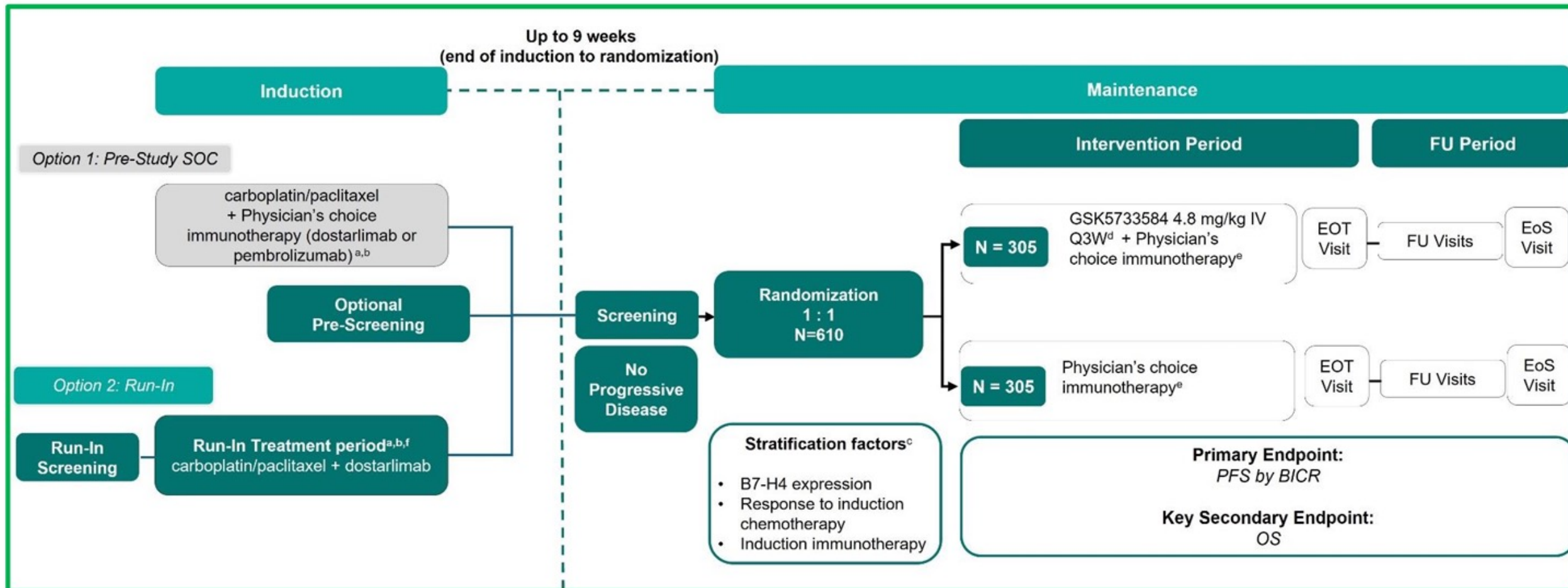
Primary Endpoint
PFS per RECIST 1.1 (BICR)
Key Secondary Endpoint
OS

Endometriumkarzinom: BEHOLD-Endometrial02

- Standardtherapie des fortgeschrittenen und **rezidierten** EC
- ist eine Chemotherapie mit Carboplatin/Taxol
 - Mit einem Immuncheckpoint-Inhibitor
 - bei pMMR zusätzlich ggf. Olaparib
- GSK 5733584 ist ein neues Antikörper-Wirkstoffkonjugat
- S.O.

A randomized, open-label, multicenter, Phase 3 study to investigate GSK5733584 in combination with immune checkpoint inhibition for maintenance treatment of participants with mismatch repair proficient (MMRp) endometrial cancer (BEHOLD-Endometrial02)

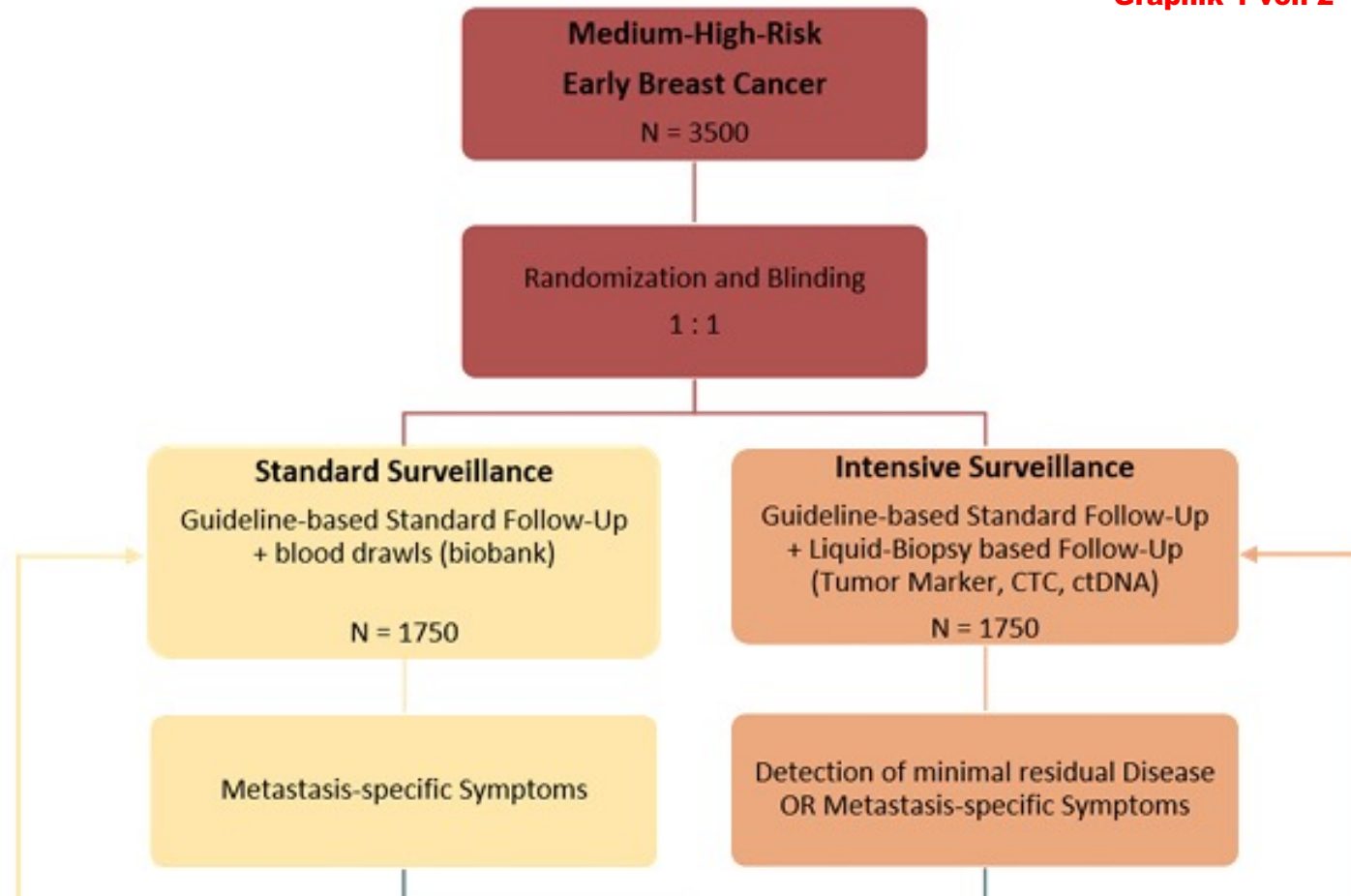
in Planung



Mammakarzinom adjuvant

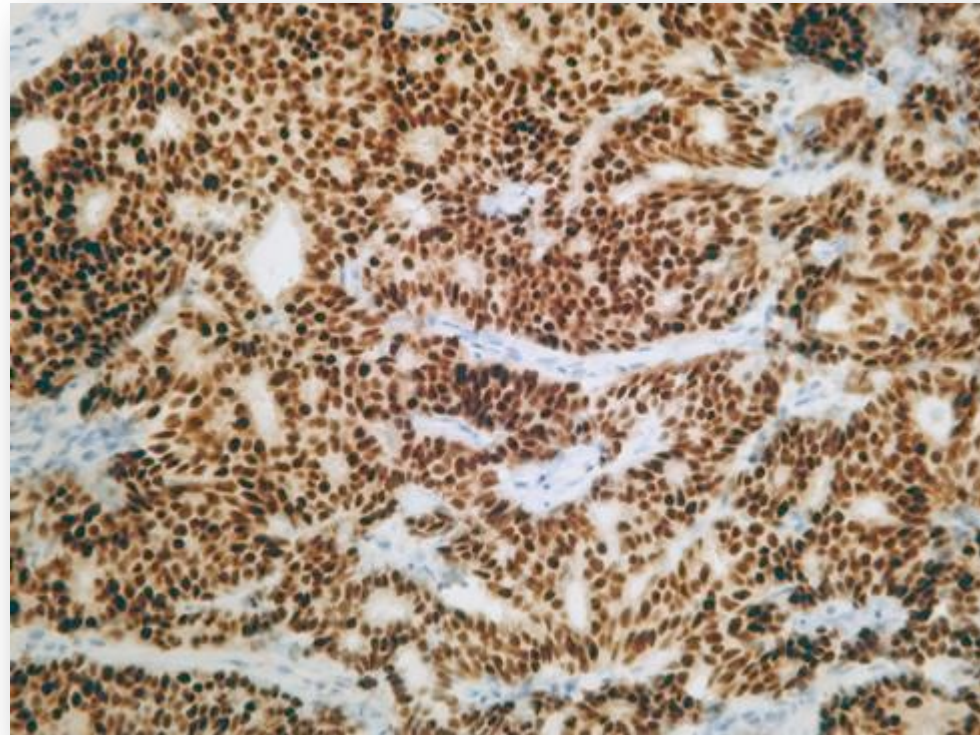
Standard Surveillance vs. Intensive Surveillance in Early Breast Cancer) – a partially double-blinded, multicenter, randomized, controlled superiority study (SURVIVE) **rekrutierend**

Graphik 1 von 2



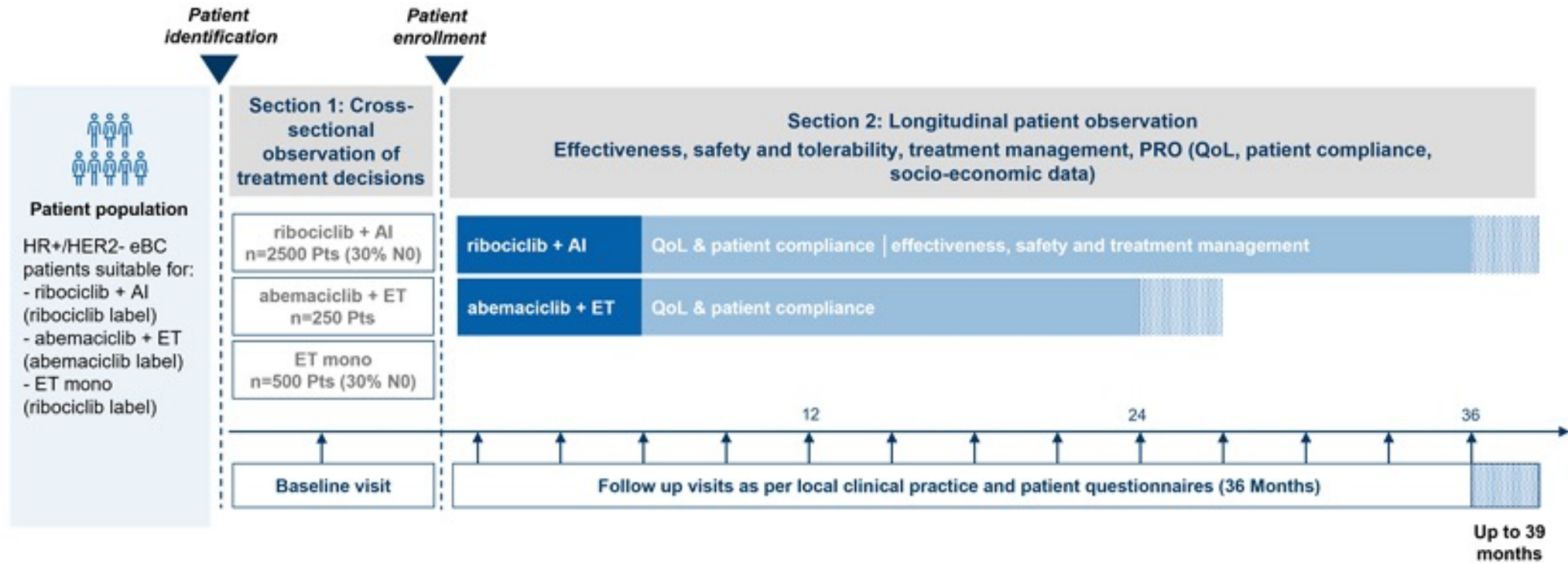
24 Patientinnen rekrutiert

HR +/-Her2-:
Luminal A und B



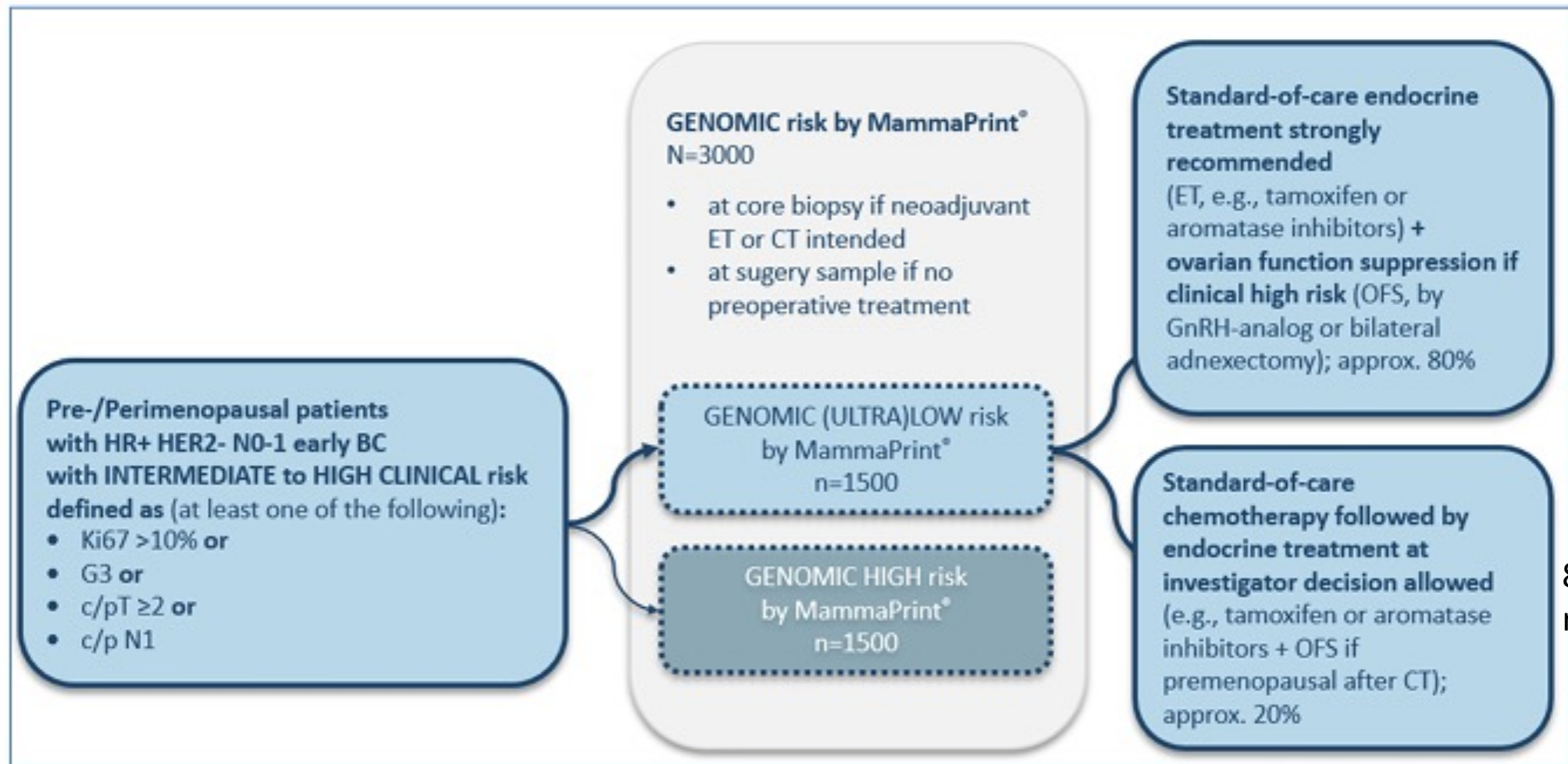
ca. 70% aller Brustkrebse

A non-interventional study for Kisqali (Ribociclib) in combination with an aromatase inhibitor in patients with HR+/HER2- stage II and III early breast cancer to evaluate real-world effectiveness, safety profile, patient compliance and quality of life (**CAROLEEN**)
rekrutierend



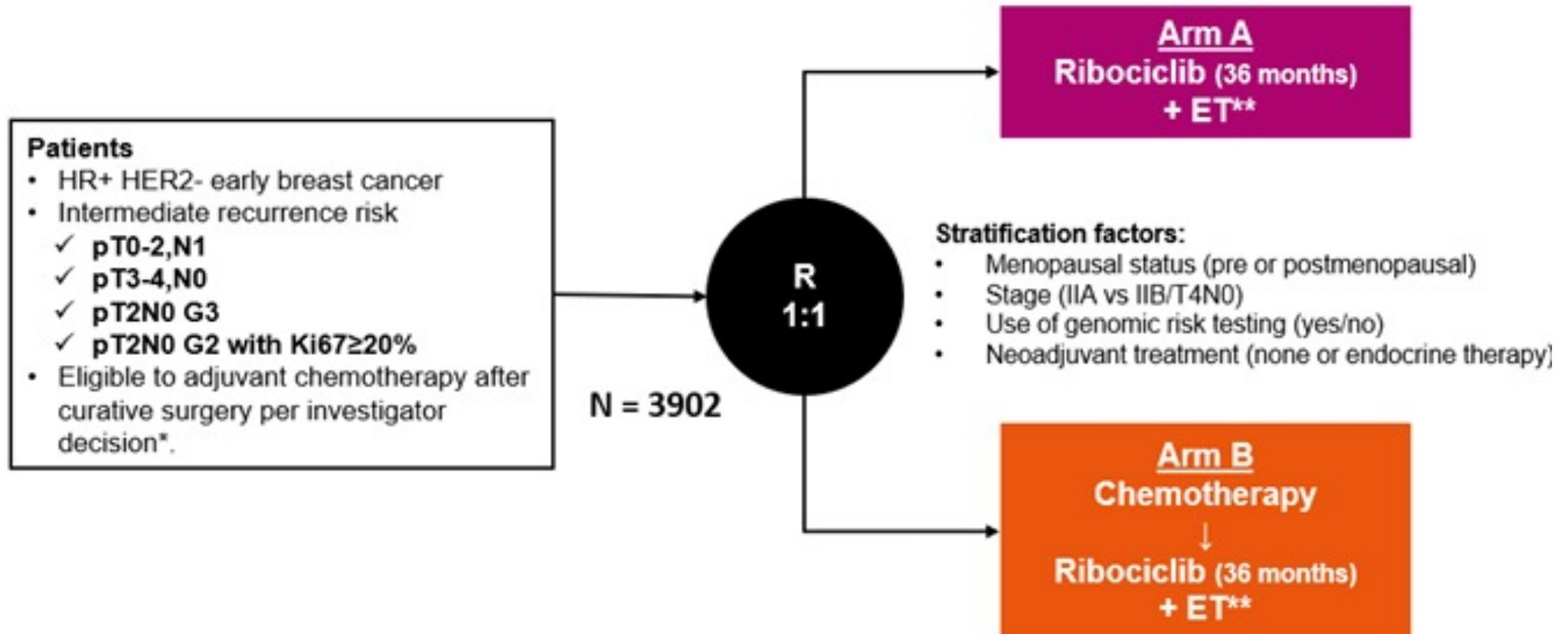
7 Patientinnen randomisiert

Real world data and long-term follow-up of **female pre- and perimenopausal patients** with luminal early breast cancer **with intermediate to high clinical risk for recurrence and low genomic recurrence-risk measured by MammaPrint®**, treated by standard-of-care endocrine treatment plus ovarian function suppression (OFS) or standard-of-care chemotherapy treatment followed by endocrine treatment) (**PROOFS-Registry**) **rekrutierend**



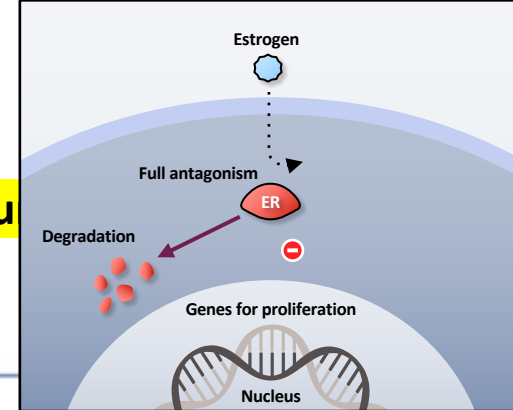
8 Patientinnen rekrutiert

No chemotherapy in intermediate-risk HR+ HER2- early breast cancer treated with Ribociclib (LEE-011) in the adjuvant setting, a non inferiority Phase III trial (**NoLEEta**) **in Planung**



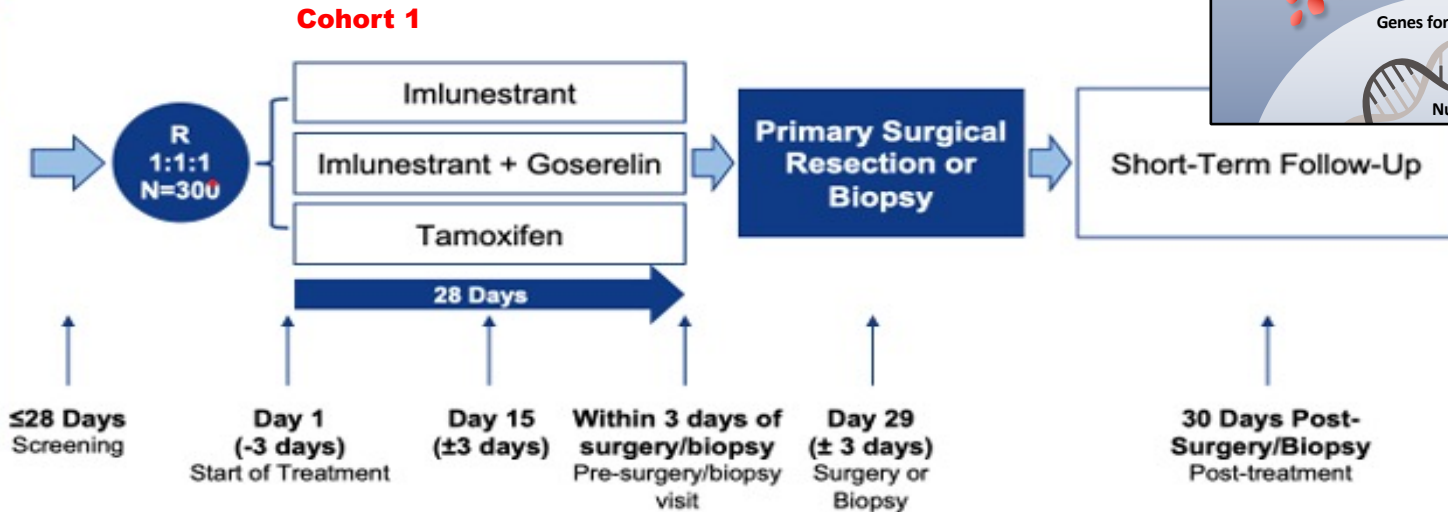
A Phase 2, Open-label Study Evaluating Imlunestrant in Premenopausal Women with Estrogen Receptor-Positive, HER2-Negative Breast Cancer (preEMBER)

in Planu



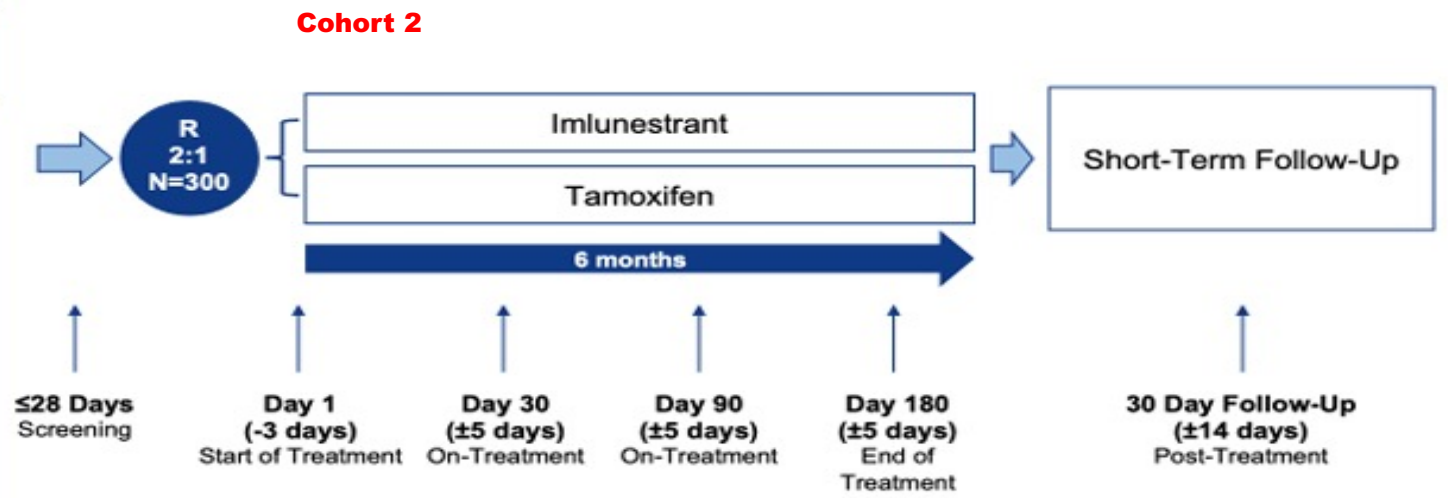
ER+, HER2- BC

- Premenopausal women
- Stage I (≥1cm)-III disease
- Ki-67 ≥10%, per local assessment
- Multifocal disease permitted if confined to 1 breast, and if each tumor is ER+, HER2-
- Scheduled for curative surgery or agrees to post-treatment biopsy

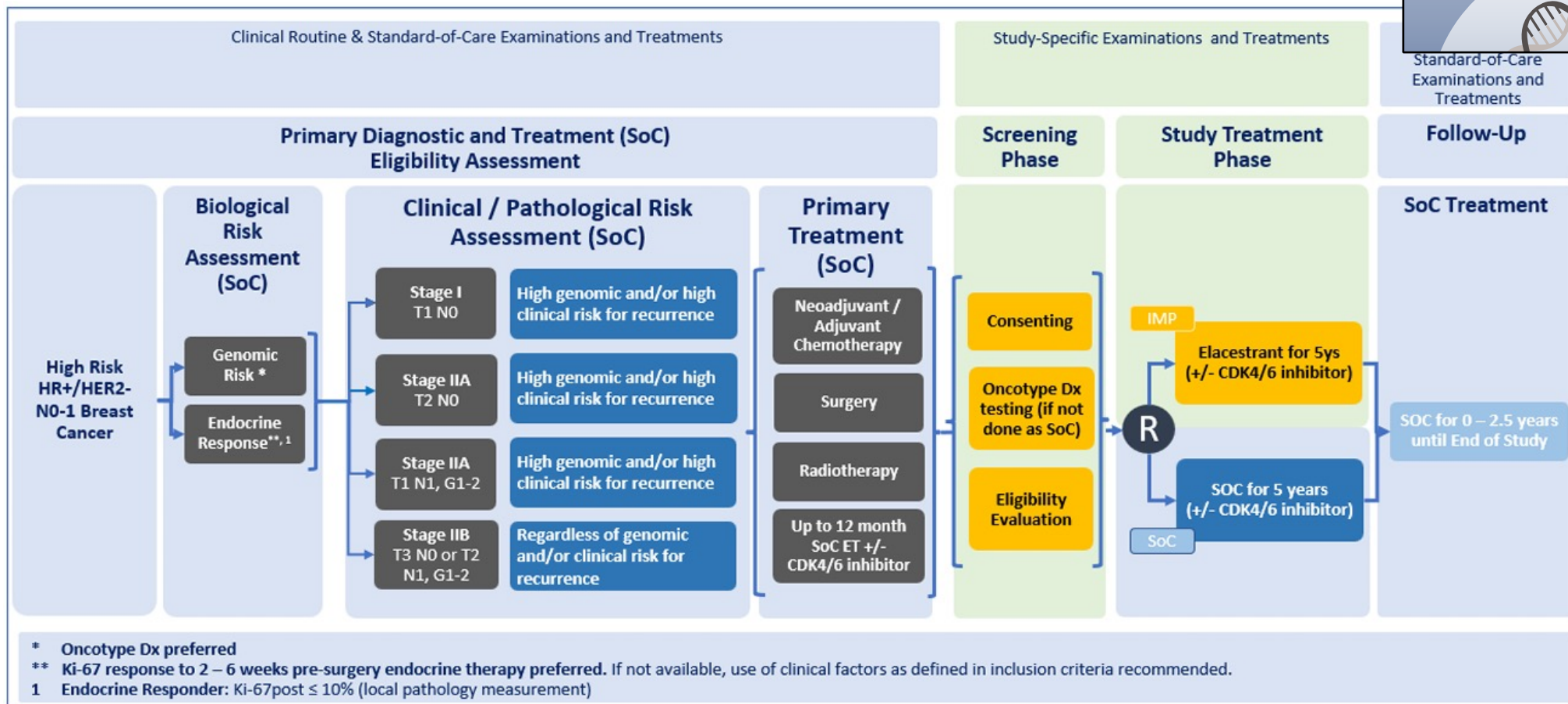
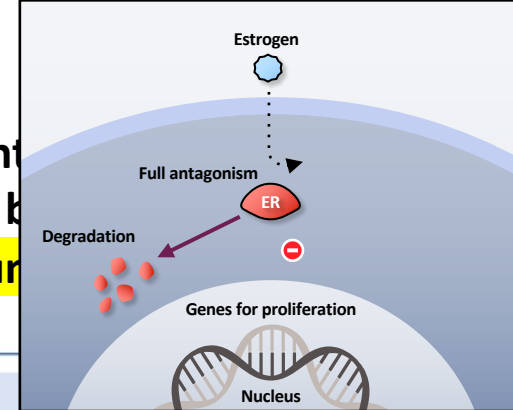


ER+, HER2- BC

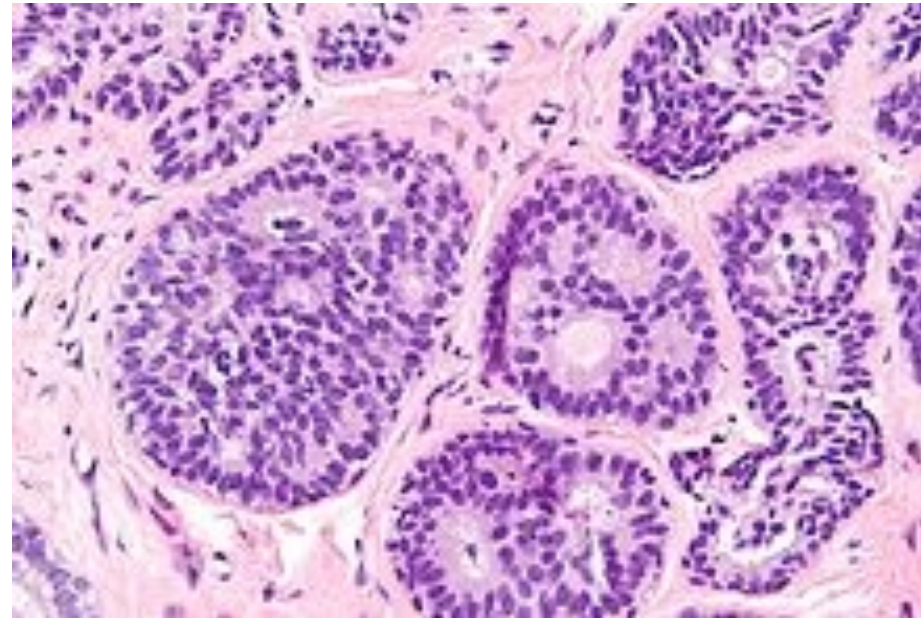
- Premenopausal women
- Early-stage, resected, invasive breast cancer without evidence of distant metastasis
- Undergone definitive locoregional therapy of the primary index breast tumor(s)
- Received at least 4.5 years of adjuvant ET, or at least 2 years of adjuvant ET with no further OFS planned



Adjuvant Dynamic marker - Adjusted Personalized Therapy comparing adjuvant Elacestrant to standard endocrine treatment in genomically and/or clinically high-risk ER+/HER2- early breast cancer (ADAPTela) in Planur

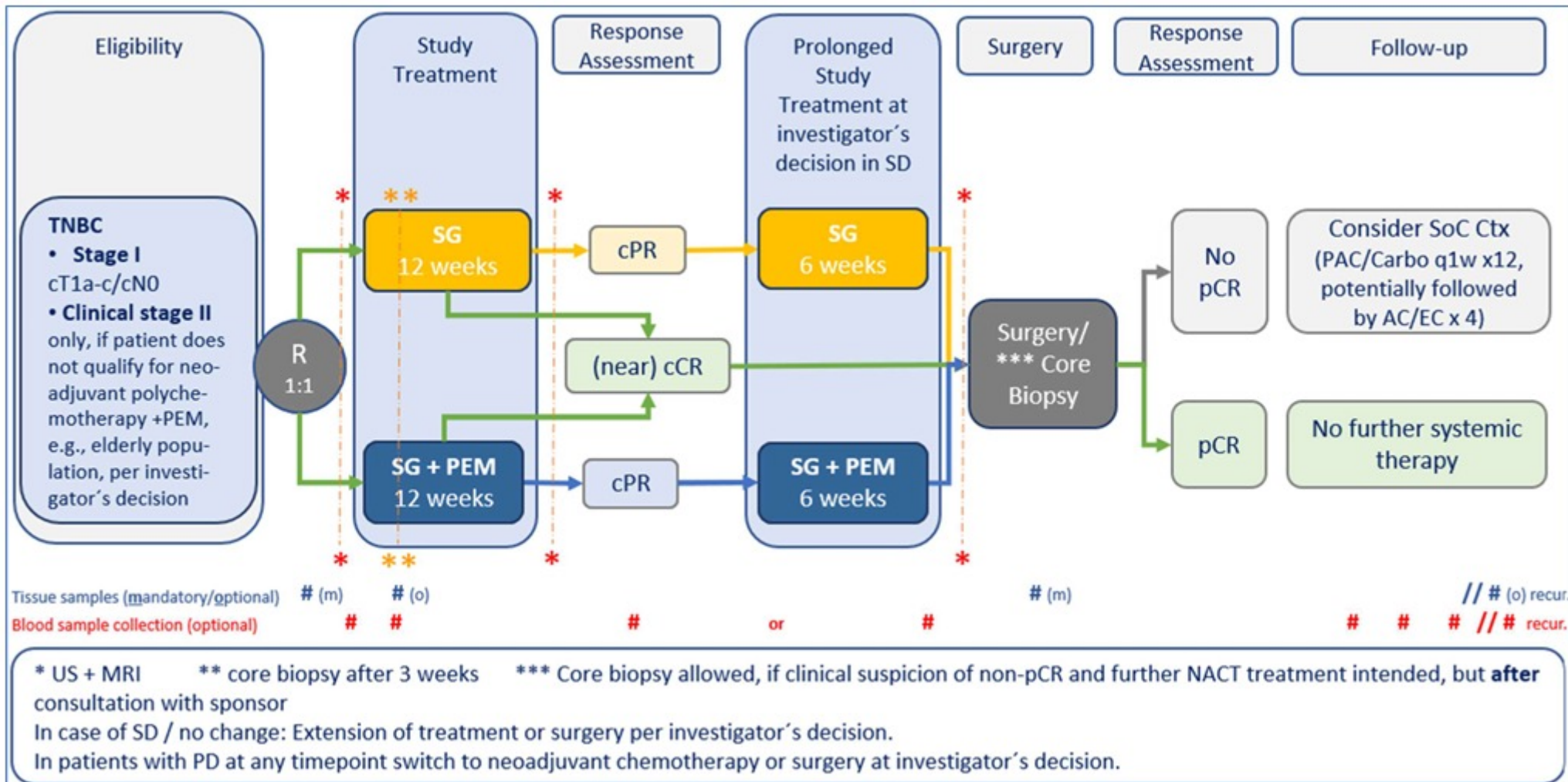


Triple Negatives Mammakarzinom



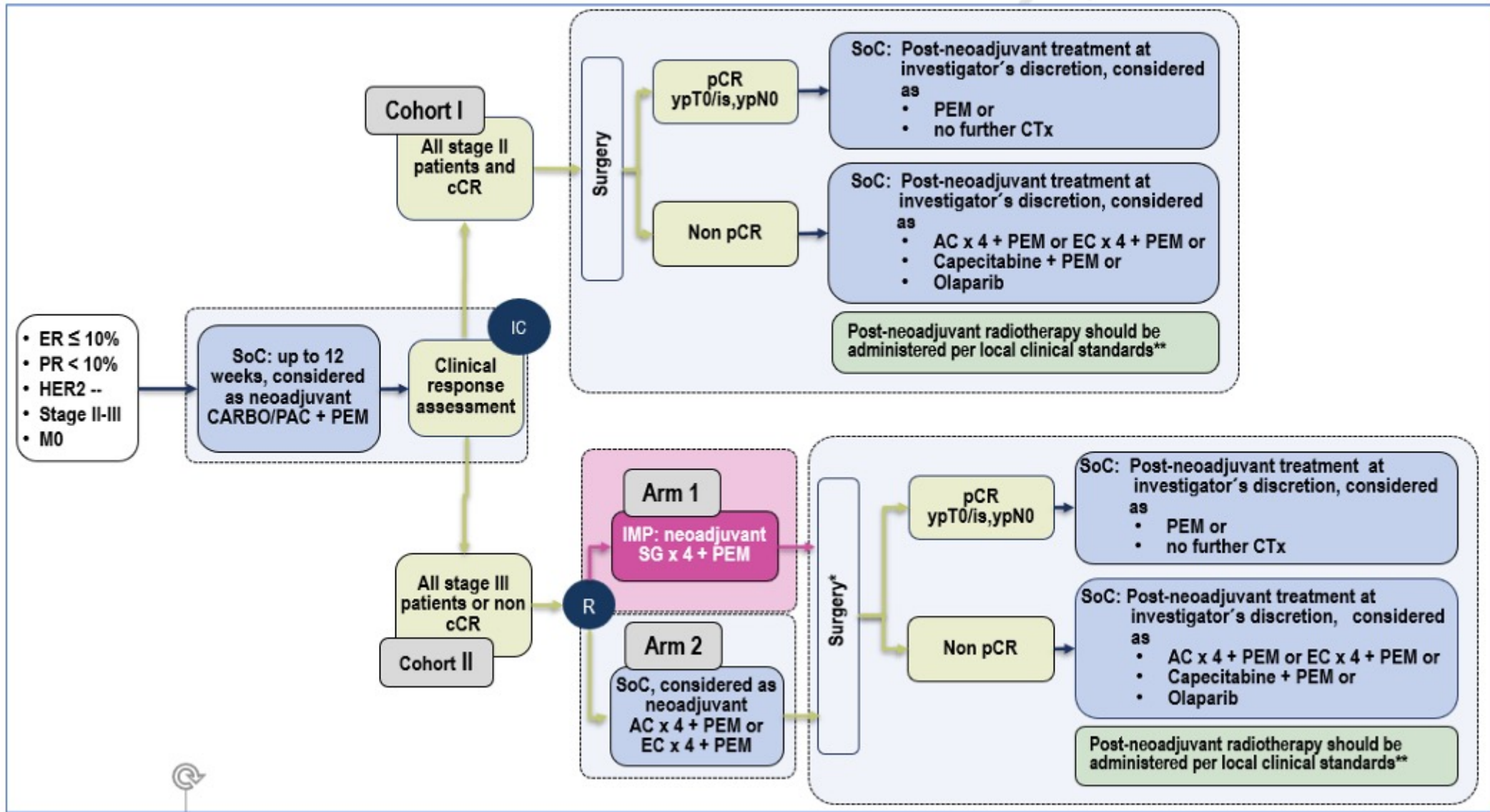
ca. 15% aller Brustkrebse

NeoAdjuvant Dynamic marker - Adjusted Personalized Therapy comparing **Sacituzumab Govitecan versus Sacituzumab Govitecan + Pembrolizumab** in low-risk, triple-negative early breast cancer (**ADAPT-TN-III**) rekrutierend

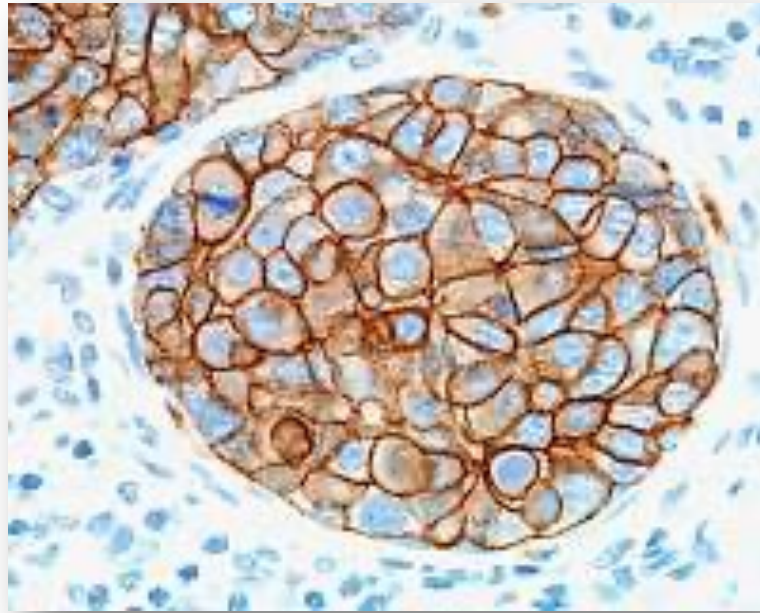


0 Patientin randomisiert

NeoAdjuvant Dynamic marker - Adjusted Personalized Therapy comparing **Sacituzumab Govitecan + Pembrolizumab vs. SoC chemotherapy** in clinical stage II-III, triple-negative early breast cancer (**ADAPT-TN-IV**) **in Planung**



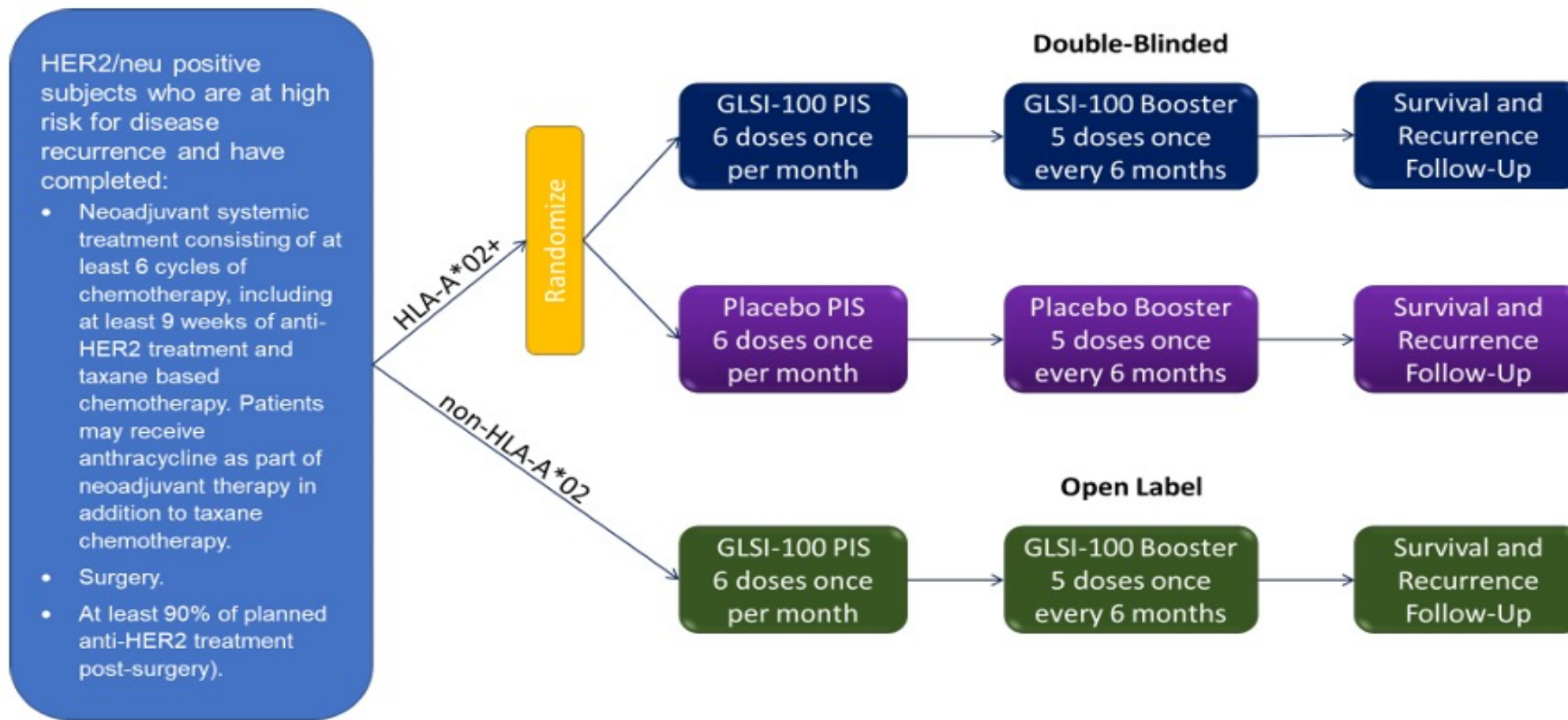
Her2 +



ca. 15% aller Brustkrebse

A Randomized, Multicenter, Placebo-controlled, Phase 3 study to Evaluate the Efficacy and Safety of **HER2/neu Peptide GLSI-100 (GP2 + GM-CSF) in HER2/neu Positive Subjects** with Residual Disease or High-Risk PCR after both Neoadjuvant and Postoperative Adjuvant Trastuzumab-based Therapy (**FLAMINGO-01**)

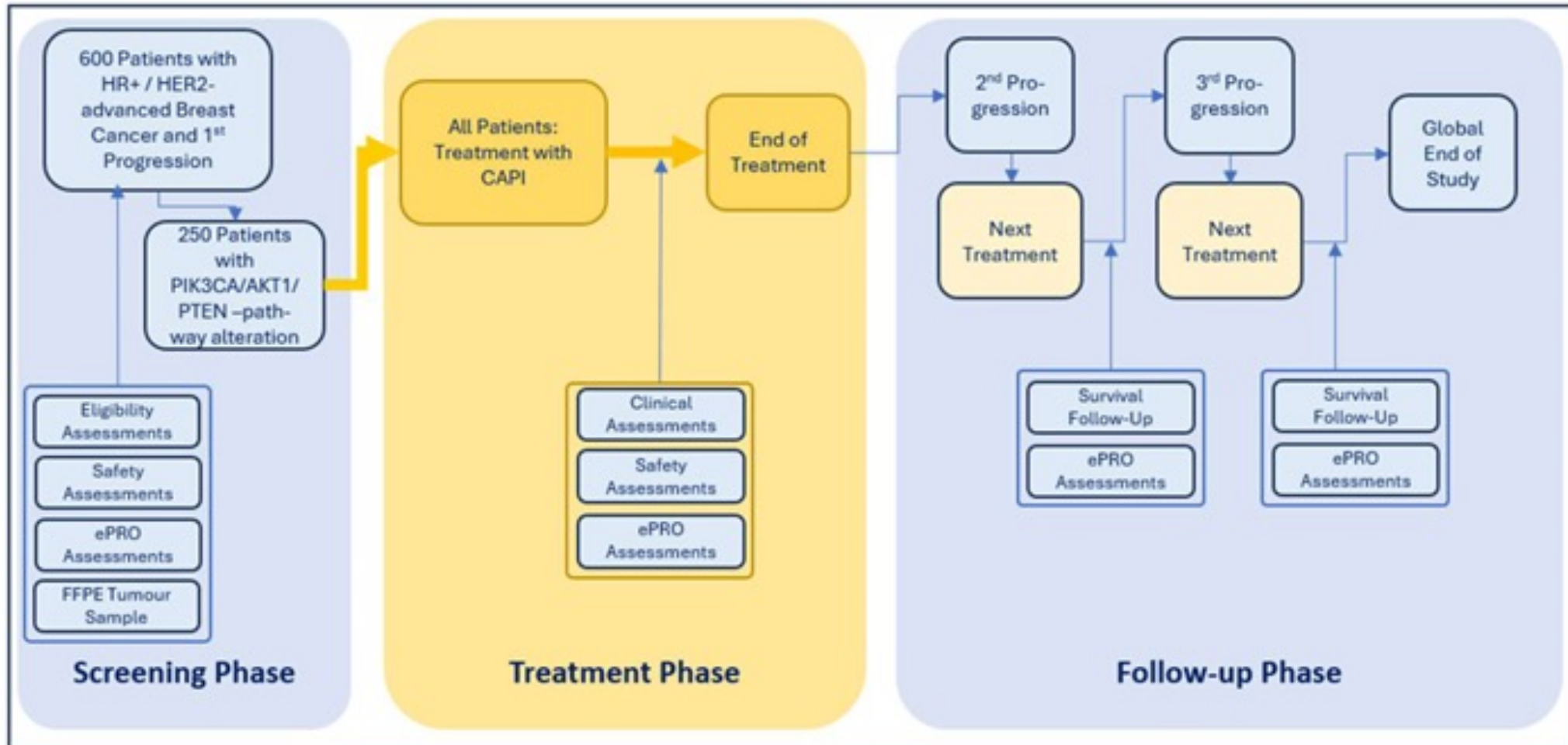
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PIS = Primary Immunization

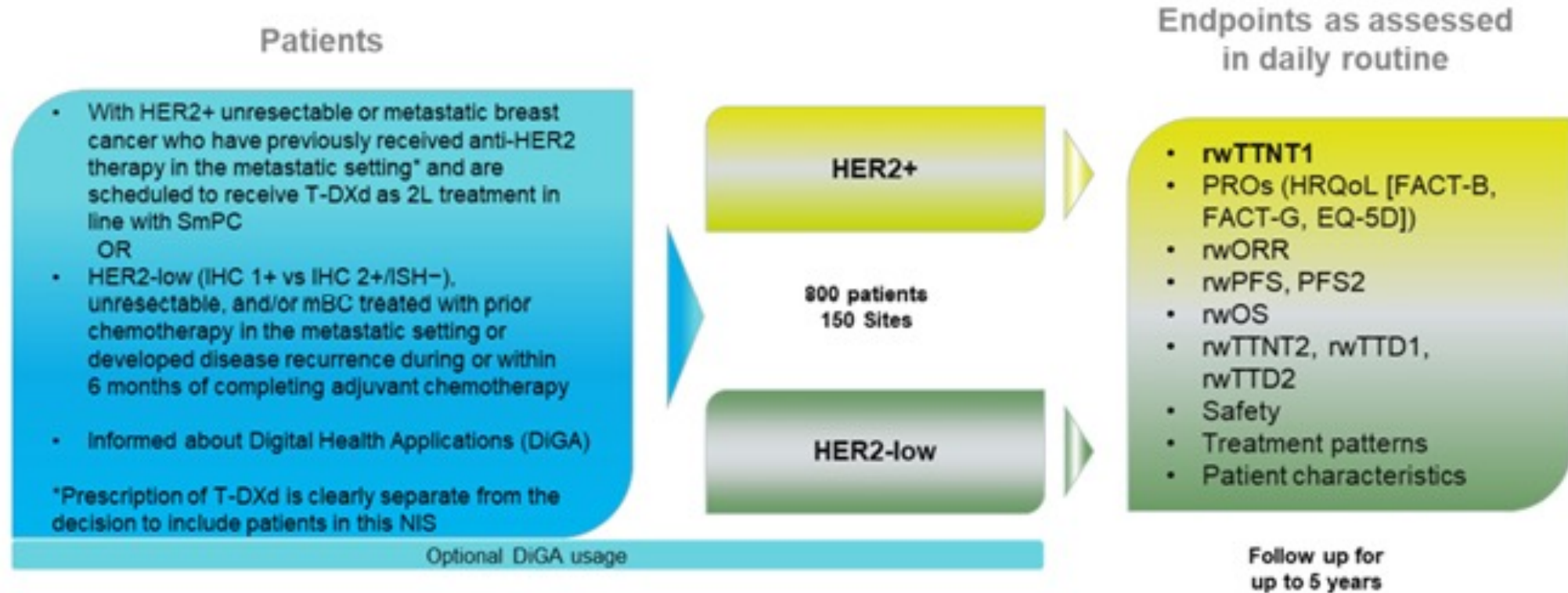
Mammakarzinom metastasiert

An interventional, open-label, phase III study to evaluate the safety, efficacy, and impact on quality of life of **capiwasertib alongside standard of-care endocrine treatment in patients with HR+/HER2-advanced breast cancer and progression on prior endocrine-based treatment (CAPIcorn)** **rekrutierend**



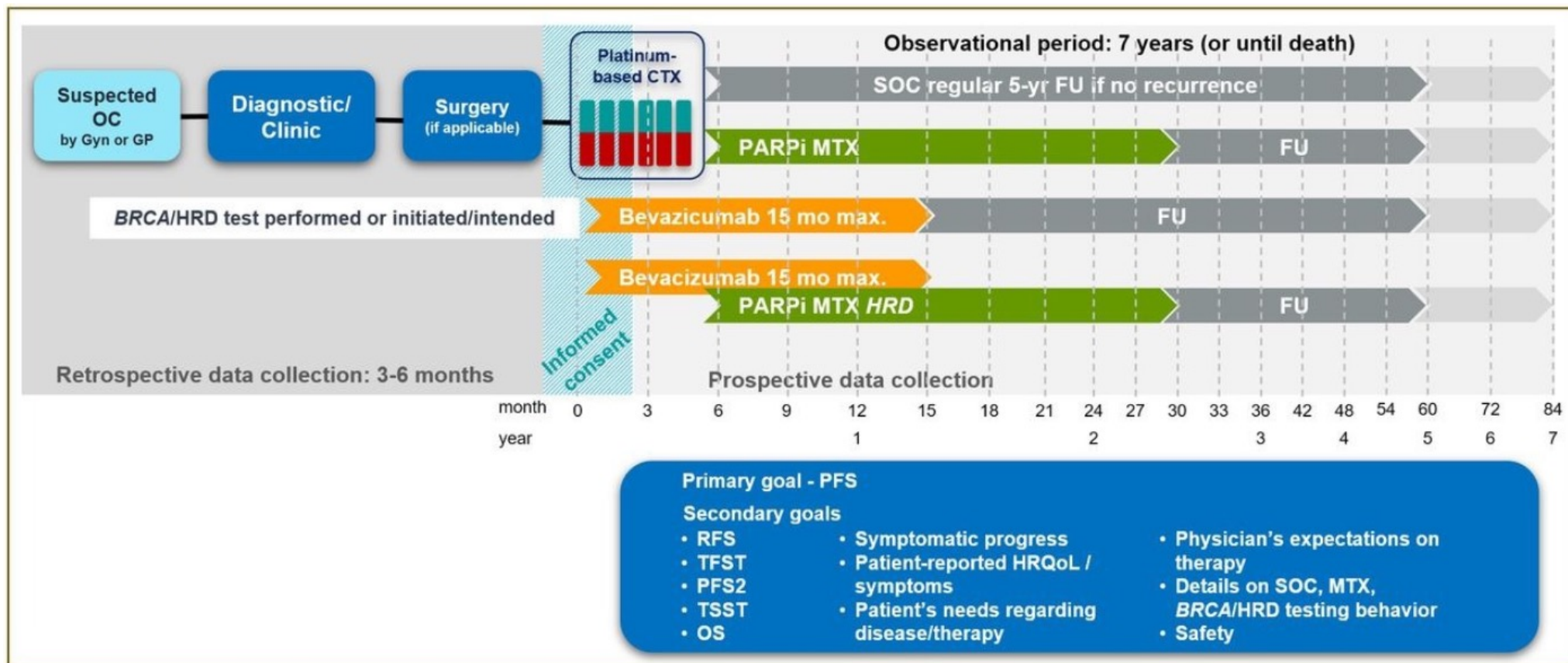
2 Patientinnen rekrutiert

Prospective non-interventional study (NIS) to examine patient-reported outcomes and **real-world clinical data in patients with HER2-positive or HER2-low unresectable or metastatic breast cancer treated with Trastuzumab Deruxtecan (PROVIDENCE)** **rekrutierend**



2 Patientinnen rekrutiert

Prospective non-interventional Study to Collect real-world clinical and patient reported OUTcome data in **ovarian cancer patients eligible for first-line platinum-based chemotherapy and intended for BRCA/HRD testing (SCOUT-1)** **rekrutierend**



3 Patientinnen rekrutiert

Mammakarzinom: weitere Registerstudien

Registerstudien

- Registerstudie Mammakarzinom des Mannes
 - Universitätsklinik Magdeburg
 - Bisher 8 Patienten rekrutiert
- Registerstudie Breast Cancer in Pregnancy
 - GBG
 - Bisher 6 Patientinnen registriert
- Registerstudie cerebral metastasiertes Mammakarzinom
 - GBG
 - Bisher 17 Patientinnen registriert

„Kitteltasche“ Studien Gyn. Onko Hildesheim 1

- Bei (fast) jedem **Ovarialkarzinom** ist eine Studien-Teilnahme möglich,
 - wenn nicht Ovar 28 (Nira +/- Beva)
 - dann Matao (+/- Let)
 - oder Scout (NIS nach BRCA- und HRD-Testung)
- **Beim Mammakarzinom adjuvant**
 - Survive/Nachsorge
 - (Wichtige Studie, erheblicher Aufwand, geringe Honorierung, vornehmlich für Patientinnen der Praxis am Bahnhofplatz)
 - Falls HR+ > Caroleen
 - (NIS bei erhöhtem Risiko mit Ribociclib und Abemaciclib adjuvant)
 - Proofs: Registerstudie nach Anwendung einer Genexpressionsanalyse
 - > Mammaprint (vorwiegend bei eigenen Pat, viel Aufwand)
 - bei TNBC gehen
 - Adapt TN III ($\leq 2\text{cm}/\text{N0}$) > SG vs SG+Pembro
 - oder TN IV (falls $> 2\text{cm}$ oder N+) > SG+Pembro vs. Chemo+Pembro

„Kitteltasche“ Studien Gyn. Onko Hildesheim 2

- **Beim metastasiert/fortgeschrittenen Mammakarzinom**
 - HRpos und PIK3CA pos > Capicorn Phase III Capivasertib
 - Bei Her2 positiv und Her2 low > T-DXd > Providence (NIS)
- **Registerstudien**
 - männliches MC (Uni MD), schwangerschaftsassoiiert (GBG), cerebral metastasiert (GBG)



Danke für die Aufmerksamkeit!

Exterior of Strax's Female Cancer Detection Mobile Unit.